September 25, 2003

OCT 3 0 2003

K033016
1 OF 2

510(k) Summary

Medtronic Models 3890, 3891, and 3892 Leads

A. *General Provisions*

Submitter's Name:	Medtronic, Inc.
Submitter's Address:	Sullivan Lake Facility 800 53rd Avenue Northeast Columbia Heights, MN 55421
Contact Person:	Pam Schaub Principal Regulatory Affairs Specialist
Classification Name:	Implanted Spinal Cord Stimulator for Pain Relief 21 CFR Section 882.5880
Common or usual Name:	N/A
Proprietary Names:	Pisces Z Quad® Model 3890 Lead, Pisces Z Quad Compact™ Model 3891 Lead, Pisces Z Quad Plus® Model 3892 Lead

B. *Name of Predicate Devices*

Medtronic Neurological	Models 3487A and 3887 Leads	K923931
Medtronic Neurological	Model 3888 Lead	K923567

C. *Device Description*

The function of the Medtronic Mattrix® and X-trel® Neurostimulation Systems is accomplished with a power source, extension (for X-trel only) and lead (electrode). The power source generates and controls the stimulation, which is delivered to the spinal cord via electrodes at the end of the lead.

The Models 3890, 3891 and 3892 Leads are lower impedance percutaneous quadripolar, implantable leads. The proximal end provides in-line four-conductor contacts that connect to the Mattrix receiver or Medtronic extension (which connects to the X-trel receiver). The proximal ends and lead bodies of all three leads are identical. Each lead model has four platinum iridium electrodes on the distal end but with variable electrode length and spacing. The electrode spacing and electrode lengths of the Models 3890, 3891, and 3892 Leads are identical to the current Models 3487A, 3887, 3888 Leads, respectively. A radio-opaque marker band at the tip of the Model 3892 Lead enhances identification when viewed in fluoroscopy. The Models 3890, 3891 and 3892 Leads are available in lengths from 10 cm to 100 cm. The Medtronic Models 3890, 3891, and 3892 Leads are packaged, sterilized, and labeled for single use only (disposable).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2003

Pam Schaub
Principal Regulatory Affairs Specialist
710 Medtronic Parkway NE
Minneapolis, Minnesota 55432-5604

Re: K033016
Trade/Device Name: Models 3890, 3891 and 3892 Leads
Regulation Number: 21 CFR 882.5880
Regulation Name: Implanted Spinal Cord Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: GZB
Dated: September 25, 2003
Received: September 26, 2003

Dear Ms. Schaub:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

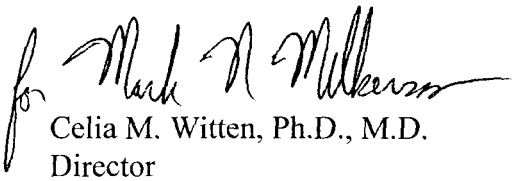
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033016

Device Name: Medtronic Models 3890, 3891, and 3892 Leads

INDICATIONS FOR USE:

The Medtronic Pisces Z Quad® Model 3890, Pisces Z Quad Compact™ Model 3891, and Pisces Z Quad Plus® Model 3892 Leads for Spinal Cord Stimulation (SCS) are indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033016